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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/830,189

04/21/2004

Brian S. Kelleher

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JONATHAN SPANGLER

NU VASIVE, INC.

4545 TOWNE CENTRE COURT

SAN DIEGO, CA 92121

EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

PAPER NUMBER

3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/830,189

Applicant(s)

KELLEHER ET AL.

Examiner

Brian Szmaj

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 October 2006 and 01 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-13, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558) in view of Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation).

Neubardt discloses a method for spinal screw insertion and further discloses applying an electrical stimulus to the first aspect of the bone; the electrical stimulus is emitted from an electrode disposed on the distal end of at least one of a probe and surgical tool; applying an electrical stimulus comprises applying a plurality of electrical stimulus pulses; the bone is disposed within one of the cervical, thoracic, and lumbar region of the patient's spine; the spinal nerve exits from successive vertebrae within one of the cervical, thoracic, and lumbar region of the patient's spine; the first aspect of the bone comprises a region within a pedicle in contact with a pedicle screw; and applying an electrical stimulus to the first aspect of the bone comprises applying the electrical stimulus to a proximal end of a bone screw inserted into the first aspect of the bone. See Figures 3 and 4; and Column 8, lines 59-67.

Neubardt however fails to disclose electrically monitoring a muscle myotome associated with the spinal nerve to determine an onset neuro-muscular response to the application of the electrical stimulus to the first aspect of the bone; communicating to a

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user an onset electrical stimulus level which causes the onset neuro-muscular response; the plurality of electrical stimulus pulses comprises current pulses that increase over time; the plurality of electrical stimulus pulses comprises current pulses that vary incrementally; the plurality of electrical stimulus pulses comprises current pulses varied incrementally within a range from 0.5 to 32.0 milliamps; the onset neuro-muscular response is an electromyography response from a muscle coupled to the spinal nerve; electrically monitoring the muscle myotome is performed through the use of an electrode electrically coupled to the muscle myotome; the muscle myotome is disposed in one of the patient's legs; and the onset neuro-muscular response is determined by assessing whether the neuro-muscular response is greater than a predetermined onset level and increasing the electrical stimulus until the determined neuro-muscular response is greater than the predetermined onset level.

Calancie et al disclose a means for determining the evoked EMG during spinal fusion surgery and further disclose electrically monitoring a muscle myotome associated with the spinal nerve to determine an onset neuro-muscular response to the application of the electrical stimulus to the first aspect of the bone; communicating to a user an onset electrical stimulus level which causes the onset neuro-muscular response; the plurality of electrical stimulus pulses comprises current pulses that increase over time; the plurality of electrical stimulus pulses comprises current pulses that vary incrementally; the plurality of electrical stimulus pulses comprises current pulses varied incrementally within a range from 0.5 to 32.0 milliamps; the onset neuro-muscular response is an electromyography response from a muscle coupled to the spinal nerve;

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electrically monitoring the muscle myotome is performed through the use of an electrode electrically coupled to the muscle myotome; the muscle myotome is disposed in one of the patient's legs; and the onset neuro-muscular response is determined by assessing whether the neuro-muscular response is greater than a predetermined onset level and increasing the electrical stimulus until the determined neuro-muscular response is greater than the predetermined onset level. See pages 2780-2782.

Since both Neubardt and Calancie et al disclose means for monitoring stimulus evoked responses, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Neubardt to include the use of electrically monitoring the EMG response, as per the teachings of Calancie et al, since it would provide a more accurate means of monitoring the status of the pedicle screw in relation to the spinal nerve. It also would have been obvious to one of ordinary skill in the art to apply the monitoring means to the arms of the patient when working on the cervical spine.

3. Claims 14 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558) and Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation) as applied to claim 1 above, and further in view of Hacker (6,334,068 B1).

Neubardt and Calancie et al, as discussed above, disclose a means for determining the nerve location through stimulation but fail to disclose communicating to a user includes visually indicating an intensity level of the electrical stimulus causing the

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onset neuromuscular response for the spinal nerve; and the visually indicating involves the use of an integrated display.

Hacker discloses an intraoperative neuroelectrophysiological monitor and further discloses communicating to a user includes visually indicating an intensity level of the electrical stimulus causing the onset neuromuscular response for the spinal nerve; and the visually indicating involves the use of an integrated display. See Figure 1; Column 4, lines 20-30; Column 8, lines 16-20 and 26-34; and Column 13, lines 29-37.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Neubardt and Calancie et al to include the use of visually indicating the stimulus level, as per the teachings of Hacker, since it would provide a means of alerting the user of the stimulus level.

4. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558), Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation) and Hacker (6,334,068 B1) as applied to claim 14 above, and further in view of Neurovision SE Nerve Locator/Monitor.

Neubardt, Calancie et al and Hacker, as discussed above, disclose a means of monitoring the muscle response of a stimulated nerve during spinal surgery, but fail to disclose illuminating lights; illuminating lights of varying colors; and each color corresponds to a predetermined warning to the user.

Neurovision SE discloses a means for stimulating and locating nerves and further discloses illuminating lights; illuminating lights of varying colors; and each color corresponds to a predetermined warning to the user. See Chapter 6: 6.1 and 6.2.

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Since Neubardt, Calancie et al and Hacker disclose means for visually alerting a user to the EMG status, but fail to disclose colored lights representing the measured status, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Neubardt, Calancie et al and Hacker to include the use of colored lights, as per the teachings of Neurovision SE, since it is well known to utilize colored lights to provide a warning.

5. Claims 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558) and Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation) as applied to claim 1 above, and further in view of Raymond et al (5,284,153).

Neubardt and Calancie et al, as discussed above, disclose a means for monitoring the EMG response to a stimulated pedicle screw, but fail to disclose the use of an audible indicator for indicating an intensity level of the response; sounding an alarm; varying the volume of the alarm; and varying the frequency of the alarm.

Raymond et al disclose a means of protecting nerves from injury during surgery, and further disclose the use of an audible indicator for indicating an intensity level of the response; sounding an alarm; varying the volume of the alarm; and varying the frequency of the alarm. See Column 7, lines 8-16.

Since Neubardt, Calancie et al and Raymond et al disclose means for monitoring the location of a medical instrument relative to a nerve, it would have been obvious to one of ordinary skill in the art to modify the combination of Neubardt and Calancie et al

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to include the use of an audible indicator, as per the teachings of Raymond et al, since it would provide an additional means of alerting the user.

### ***Response to Arguments***

6. Applicant's arguments filed October 16, 2006 have been fully considered but they are not persuasive.

The Applicants have amended the independent claim to attempt to overcome the combination of Neubardt and Calancie et al, through the use of "automatically" determining the muscular response without requiring anyone to interpret the results to a surgeon. Calancie et al discloses the use of a neurophysiologist to interpret the acquired signals to determine the muscular response. However, the current claim language, when interpreted broadly, is still disclosed by the combination of Neubardt and Calancie et al. The setup of Calancie et al receives EMG signals in response to a nerve stimulation, and therefore automatically determines the muscle response after stimulation and either displays the muscle response to a neurophysiologist or provides an acoustic output of the muscle response, which would also provide an automatic determination of a muscle response that can be relayed directly to a surgeon instead of a neurophysiologist (p. 2781, last 3 lines under the paragraph titled Recording and Stimulation).

The Applicants also argue neither Neubardt nor Calancie et al disclose communicating to a user an onset electrical stimulus level. The current claim language fails to differentiate to whom the onset electrical stimulus level is communicated. The



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onset level can be communicated to the neurophysiologist, as disclosed in Calancie et al, and then can be relayed to the surgeon. Therefore, the current claim is still disclosed by the combination of Neubardt and Calancie et al.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

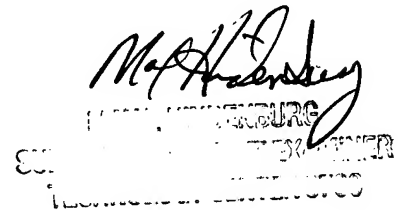
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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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